K002382

Analytical Industries Inc.

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MAR 1 4 2001

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness is being submitted in with requirements of SMDA 1990 and 21 CFR 807.92.

Oxygen Analyzers Based on Electrochemical Sensors

In an oxygen analyzer capable of displaying the concentration of oxygen in percent by volume units, the current signal output generated by the electrochemical oxygen sensor is fed into an I-E converting differential amplifier. The voltage signal is then fed to a potentiometer to adjust the signal proportional to the oxygen concentration present. The signal is then filtered by using a conventional low-pass filter. The signal is then compensated for changes attributed to ambient temperature variations. This signal is then fed to a digital display for read out. The span or calibration adjustment, filtering and temperature compensation of the signal can be achieved in any order and does not effect the accuracy of the final signal value.

The electronics design incorporated into Analytical Industries Inc. model AII 2000 % Oxygen Analyzer is similar to that described above. The analyzer's performance has been verified within the established specifications (Section 6) using an oxygen sensor manufactured by Analytical Industries Inc.

The electrochemical galvanic fuel cell type oxygen sensors are extensively being used to measure oxygen concentrations in gas streams. The galvanic fuel cell oxygen sensor referred to as oxygen sensors are very specific to oxygen concentrations and produce an electrical current signal proportional to the concentration of oxygen. The electrical current signal varies linearly with oxygen concentration. The signal also varies with changes in ambient temperature. The temperature coefficient is typically 2.54% of the signal per degree C change in temperature. The temperature dependent current signal is compensated by using a resistor-thermistor network. With a proper resistor-thermistor network, the signal can be compensated to within $\pm$5% of the oxygen reading over 0-50 degrees C temperature range.

Analytical Industries Inc. is a manufacturer of oxygen sensors and has previously received clearance under a separate 510(k) Application to market the sensors alone as direct replacements for those being marketed by other manufacturers.

Inasmuch as the oxygen sensor is a critical component of an oxygen analyzer it is important to understand its critical characteristics and principle of operation.

Characteristics of Galvanic Fuel Cell Type Oxygen Sensors

Galvanic type oxygen sensors consist of six basic components: 1) Oxygen sensing cathode, 2) Anode, 3) Electrolyte, 4) Oxygen diffusion limiting barrier, 5) Housing, 6) Electrical leads from the cathode and the anode to a measuring instrument. In general, the size of the sensing cathode, amount of the anode, thickness of the oxygen diffusion barrier and the size and shape of the housing vary depending on the sensitivity of measurement, speed of response and operating life required.

The rate of diffusion of oxygen to the cathode is limited by the thickness of the gas barrier such as a Teflon membrane. The total amount of oxygen per unit time that reaches the cathode surface is

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proportional to the partial pressure of oxygen in a gas mixture. The rate of reaction i.e. total number of oxygen molecules being reduced per unit time is inversely proportional to the thickness of the gas barrier and directly proportional to the partial pressure of oxygen in a gas mixture.

The flow of electrons from the anode to the sensing cathode via an external circuit results in a measurable current proportional to the amount of oxygen in the gas phase. The electrolyte, acidic or alkaline, carries the charge to and from the electrodes within the sensor. For each oxygen molecule to be reduced, two lead atoms are consumed (oxidized). The performance of such oxygen sensors is characterized by: 1) speed of response expressed typically as 90% of the final value with any step change in oxygen concentration, 2) operating temperature range, and, 3) linearity of response with changing oxygen concentration. Other less critical characteristics include dimensions and operating life.

Analytical Industries Inc. intends to market oxygen analyzers based on galvanic fuel cell type sensors that have the same principle of operation as disclosed in US Patent Nos. 3,429,796 and 3,767,552. The components of the oxygen sensors Analytical Industries Inc. intends to market are essentially the same as those currently being marketed by other manufacturers. It is worthwhile to point out that the proliferation of apparently different models of oxygen sensors can be attributed to minor modifications in dimensions, connections and packaging. However, the principle of operation and the basic components remain the same.

By verifying the most critical specifications of the Analytical Industries Inc. oxygen analyzer and comparing the results with the analyzer specifications of predicate devices published by other manufacturers, it is evident that the Analytical Industries Inc. AII 2000 % Oxygen Analyzer is substantially equivalent to those marketed by Teledyne, Hudson and MSA (Mine Safety Appliances/Catalyst Research).

Conclusion

From the foregoing discussion, the device Analytical Industries Inc. intends to market has the same intended use and the same technological characteristics as predicate devices. Further, it has been demonstrated that the device performs within the specifications of Analytical Industries Inc. Therefore, it can be concluded the Analytical Industries Inc. device is as safe and effective as the predicate devices and does not raise questions regarding safety and effectiveness from the predicate devices. Therefore, Analytical Industries Inc. respectfully requests the device they intend to market be accepted as substantially equivalent to predicate devices.

Patrick J. Pundible
Vice President

7/25/00

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2001

Mr. Patrick J. Prindible
Analytical Industries Inc.
2855 Metropolitan Place
Pomona, CA 91767

Re: K002382
'All 2000' % Oxygen Analyzer
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: January 29, 20001
Received: February 1, 2001

Dear Mr. Prindible:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 5

510(k) Number (if known): K002382

Device Name: Oxygen Analyzer

Indications For Use:

The AII 2000 % Oxygen Analyzer is intended to measure and display the concentration of oxygen in breathing gas mixtures. The analyzer is intended for use only to spot check and verify the oxygen concentration in breathing gas mixtures controlled and set by other medical devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X PRESCRIPTION USE —OR— OVER-THE-COUNTER USE ____

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number _____